UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

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| IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION | MDL No. 2545 |
| This Document Relates to All Cases | Master Docket Case No. 1:14-cv-01748<br>Hon. Judge Matthew F. Kennelly |

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR PROPOSED CASE SCHEDULE**

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## INTRODUCTION

The key difference between Plaintiffs' and Defendants' proposed schedules is how they treat the question of general causation—whether testosterone replacement therapies (TRTs) are even capable of causing the complained-of injuries. Plaintiffs' proposal all but ignores general causation, by only allowing the parties to address it one month before trial, when all of the pretrial work in the litigation already will be done. Defendants' proposal, attached as Exhibit 1, prioritizes discovery about general causation and provides for an earlier date on which the Court can decide the issue, before discovery unrelated to general causation and before the selection and discovery of plaintiffs for bellwether trials. Defendants' proposal may allow the parties and the Court to avoid a great deal of that pretrial work altogether, and at the very least will streamline the litigation and focus the parties on the injuries—if there are any—for which the Court finds the plaintiffs' claims may go forward.

As the Manual for Complex Litigation § 22.634 explains, general causation is an issue that may "be taken up early in the litigation" to gain efficiencies. For that reason, it is common in MDLs and similar cases for courts to prioritize general causation, particularly in cases like this one where there will be significant challenges to the admissibility of expert testimony that claims to link TRTs with the alleged injuries. For the Court's convenience, eight recent examples of schedules providing for early general causation *Daubert* proceedings are discussed below.

This litigation is particularly appropriate for a causation-first schedule. Plaintiffs' Co-Lead Counsel conceded, in a brief supporting this MDL's creation, that all TRT cases "***turn on one threshold question of fact*** … whether … testosterone therapies are ***capable of causing the injuries*** suffered by the plaintiffs, including heart attacks, pulmonary emboli, and strokes." Movant's Reply Brief, MDL 2545, Doc. 110, at 11 (J.P.M.L.) (emphasis added). The brief also candidly recognized "there will be significant challenges to the validity of the science supporting the causal relationship between the use of the product and the resulting harm." (*Id*. at 6-7.)

The FDA's most recent public statement on TRTs addressed the exact issue that would be at the heart of an early general causation challenge, by concluding that "there is insufficient

evidence of a causal link between testosterone therapy and adverse cardiovascular outcomes." The FDA found that the four studies on which Plaintiffs principally rely in their proposed Amended Complaints "did not demonstrate that TRT is associated with an increased risk of CV [cardiovascular] events." The FDA also recognized that randomized controlled trials "have shown that testosterone therapy generally improves some biomarkers of cardiovascular health."

Earlier this month, the EU's European Medicines Agency concurred, because it "did not find consistent evidence that the use of [TRTs] increases the risk of heart problems"; in fact, "the lack of testosterone itself could increase the risk of heart problems."[1]

Given those views from the expert drug regulators, Plaintiffs' ability to offer reliable expert testimony on the threshold issue of general causation should be addressed early in the litigation, not, as Plaintiffs' propose, on the eve of trial after discovery on all other topics is done. It is no answer to say, as Plaintiffs might, that perhaps future science might support causation. "[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy*, 78 F.3d 316, 319 (7th Cir. 1996) (excluding an expert who failed to account for "well-known causal factors in … heart attacks" such as "smoking, fatty diet, high blood pressure, [and] diabetes"); *see also Moore v. Ashland Chem.*, 151 F.3d 269, 276 (5th Cir. 1998) ("the law cannot wait for future scientific investigation and research"). As Judge Fallon wrote, "science may one day determine with sufficient reliability that a causal relationship exists … but it is not there yet and may never be." *In re Propulsid*, 261 F. Supp. 2d 603, 615 (E.D. La. 2003). If there is no reliable science to allow these claims to be presented to a jury, the parties ought to find out as soon as reasonably possible.

The efficiencies to be gained by addressing general causation first are obvious. If Plaintiffs fail to offer reliable expert testimony regarding general causation, these cases will be over without the need for the parties or the Court to expend any further time or resources. Or if

[1] Even Health Canada, which did require addressing cardiovascular risk in the prescribing information for TRT products in Canada, found that, far from proving a link between TRT and cardiovascular events, the studies only "suggest[] the possibility that cardiovascular problems" may occur.

the Court finds that there is reliable expert testimony regarding general causation for some injuries but not others, the parties will know what types of plaintiffs to include in the bellwether pool and what types of plaintiffs to exclude. These benefits are not just for Defendants. Plaintiffs and the Court stand equally to gain. There is no disadvantage to Plaintiffs, because the general causation fact and expert discovery that Defendants' proposal prioritizes in the schedule will have to be done at some point no matter what schedule is used. Putting it first simply focuses everyone's attention on the key threshold question.

Plaintiffs' proposal, by saving the threshold question of causation for the very end of the case, puts the parties and Court at substantial risk of taking a great deal of unnecessary discovery and participating in unnecessary proceedings. Discovery would be taken from Defendants on topics other than general causation, which would likely prove unnecessary. And all of the discovery of the bellwether Plaintiffs would also proceed, including the *hundreds* of potentially unnecessary bellwether-related depositions called for in Plaintiffs' schedule.

In sum, a schedule that provides for an earlier ruling on general causation benefits both sides, saves the resources of the Court, disadvantages no one, and will help to secure the just, speedy, and less expensive determination of these cases. There are serious doubts about the threshold validity of Plaintiffs' claims, which Defendants will spend a great deal of time and money addressing, and it is sensible and fair that general causation should be addressed first so that unnecessary and wasteful future costs can be avoided.

As explained below, Plaintiffs' proposed schedule also suffers from serious flaws beyond its treatment of general causation, including a self-proclaimed "rocket docket" that seeks premature bellwether selection, no discovery cut-off, the first trial in only 18 months, and, finally, a single-tier trial schedule that includes all Defendants without considering that there are more AndroGel only cases currently pending. For all of these reasons, Defendants respectfully urge the Court to enter the case management order attached hereto as Exhibit 1.

## BACKGROUND

### A. Plaintiffs' injuries

Plaintiffs' injuries—heart attack, stroke, and venous blood clots—are tragically common among men without regard to whether they use TRTs, and are associated with well-known risk factors.[2]

***Heart attack***: the leading cause of death in the U.S, killing over 600,000 people each year. Major risk factors include gender (male), age, family history, smoking, and high blood cholesterol, blood pressure, blood sugar, physical inactivity, body weight, stress, and alcohol use.

***Stroke***: the leading cause of adult disability in the U.S. and the fourth leading cause of death. Roughly 800,000 strokes kill around 130,000 Americans each year. Major risk factors include race, age, family history, high blood pressure (which is the leading cause), smoking, diabetes, artery disease, high blood cholesterol, poor diet, physical inactivity, and alcohol use.

***Venous blood clots***: including deep vein thrombosis (clot in a deep vein, often the leg) and pulmonary embolism (clot that travels to the lung), occur in 300,000 to 600,000 Americans each year, resulting in 60,000 to 100,000 deaths. Risk factors include family history, genetic defect, age, smoking, being overweight, bed rest or prolonged sitting, cancer, dehydration, injury to a vein, diabetes, heart failure, atherosclerosis (build-up of plaque in the arteries), and others.

### B. The FDA's (and European Union's) consistent conclusions about TRTs

The FDA recently examined the issue of TRT safety several times, each time concluding that science does not show TRTs are responsible for cardiovascular problems.

- **2010-2011:** The FDA first examined the issue. After "weighing all available evidence," the FDA concluded that "there was insufficient evidence of a cardiovascular risk associated with TRT to warrant a regulatory action." The FDA added "that the studies did not demonstrate that TRT is associated with an increased risk of CV events," but rather that TRTs offered "the potential to decrease the risk of adverse CV events."[3]

[2] The information in this section comes from the websites of the Centers of Disease Control, National Institutes of Health, the American Heart Association, and the Mayo Clinic.

[3] Briefing Book, Intro. Mem.: Epidemiology at 2, *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM412536.pdf.

- **April 2011**: Later that year, the FDA approved the sale of AndroGel in a new concentration,[4] which would not have happened if TRTs caused cardiovascular problems.

- **July 2014**: In response to a petition, the FDA evaluated all of the existing studies—including all of the studies identified in the proposed Amended Complaints—and again concluded that "there is insufficient evidence of a causal link between testosterone therapy and adverse cardiovascular outcomes" to require the requested warning on TRTs about cardiovascular problems. The FDA observed that "[t]here is a growing body of evidence regarding the association between *low* baseline testosterone and poor cardiovascular health" (emphasis added). Similar to its 2010 findings, FDA again concluded, "Randomized controlled trials have shown that testosterone supplementation generally *improves* some biomarkers of cardiovascular health" (emphasis added).[5]

- **August 2014:** In its Briefing Book released in advance of the FDA Advisory Committee meeting on TRT, FDA found that "[o]bservational studies generally have shown that low serum testosterone concentrations are associated with the worsening of biomarkers of cardiovascular health, such as the progression of atherosclerosis, adverse lipid profile . . . and high blood pressure." It further found that "[b]ecause of important limitations, the available epidemiological studies do not provide convincing evidence that TRT is associated with adverse CV outcomes."

- **October 2014:** The European Medicines Agency, echoing the FDA's conclusions, "did not find consistent evidence that the use of [TRTs] increases the risk of heart problems," noting that "the lack of testosterone itself could increase the risk of heart problems."[6]

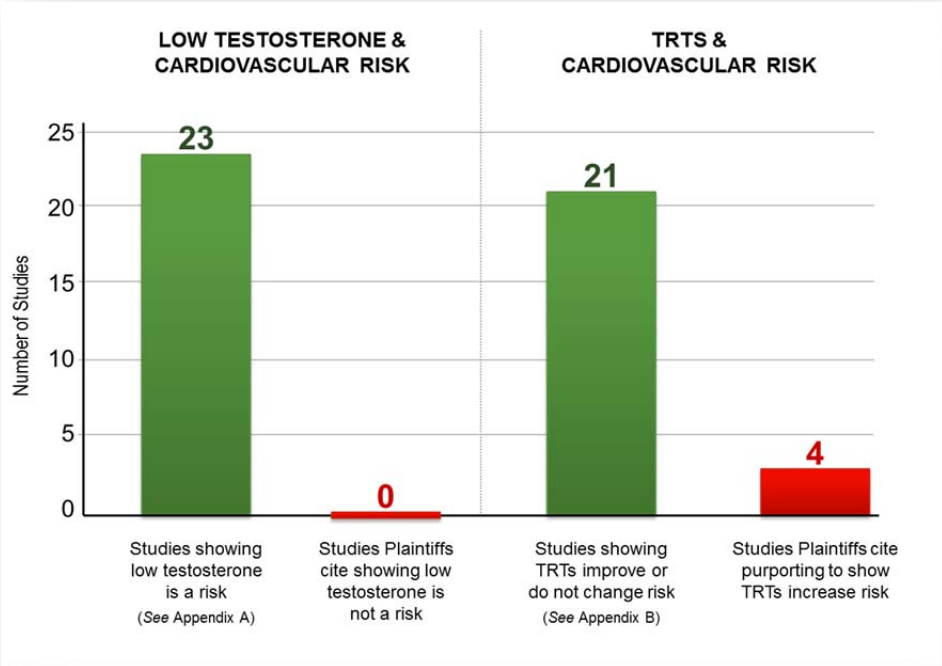
### C. The studies

As an illustration of the one-sided evidence on general causation that has supported these recent regulatory pronouncements, the following chart divides the relevant studies into two groups. The left side shows in green studies finding that *low* testosterone is a cardiovascular risk; and in red studies Plaintiffs cite finding it is not. The right side shows in green the studies finding that TRTs lessen or leave unchanged cardiovascular risk; and in red studies Plaintiffs cite showing an increase in risk.

[4] *See* AndroGel 1.62% Approval Package (April 29, 2011), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022309Orig1s000Approv.pdf.

[5] FDA Denial at 3 (July 16, 2014), *available at* http://www.regulations.gov/contentStreamer?objectId=09000064817b16ee&disposition=attachment&contentType=pdf.

[6] European Medicines Agency, *PRAC review does not confirm increase in heart problems with testosterone medicines* (October 10, 2014), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Testosterone_31/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500175213.pdf.




The left side shows that *low* testosterone is plainly a risk factor for cardiovascular problems. As one study put it, "[s]everal longitudinal population studies have reported that a low testosterone at baseline is associated with an increase in all-cause mortality."[7] Against all 23 studies, listed for the Court's convenience in Appendix A, Plaintiffs have cited nothing.

With low testosterone *increasing* the risk of cardiovascular problems, one would expect that raising testosterone levels would not worsen the risk, and my even decrease the risk—the opposite of Plaintiffs' causation theory. Indeed, as shown on the right side of the chart, at least 21 studies contradict Plaintiffs. For example, one study found that "testosterone treatment was associated with . . . a 39% decreased mortality risk."[8] Another found that "testosterone therapy .

[7] V. Muraleedharan, *Testosterone deficiency is associated with increased risk of mortality and testosterone replacement improves survival in men with type 2 diabetes*, 169 EUROPEAN J. ENDOCRINOL. 725, 725 (2013).

[8] Molly M. Shores et al., *Testosterone Treatment and Mortality in Men with Low Testosterone Levels*, 97 J. CLIN. ENDOCRINOL. METAB. 2050 (2012).

. . improve[s] several important cardiometabolic risk factors . . . ."[9] Yet another study found that "testosterone therapy had no significant effects on all-cause mortality, …cardiovascular events, or cardiovascular risk factors," a result "consistent with prior reviews."[10]

For the contrary position, blaming TRTs for extremely common injuries, Plaintiffs cite four faulty studies[11] purporting to link TRT use to an increase in cardiovascular risk. Those studies are covered in Defendants' motion to dismiss and briefly summarized here:

The ***NEJM* study** (2010) was about whether TRT improved mobility in older men with heart disease and other serious ailments. The authors said the trial did *not* provide reliable evidence regarding the safety of TRTs: "[t]he small size of the trial and the unique population prevent broader inferences from being made about the safety of testosterone therapy." They conceded that their observed connection between TRTs and cardiovascular problems "may have been due to chance alone." The FDA said the *NEJM* study's design "prevented a meaningful interpretation of drug causality."[12]

The ***JAMA study*** (2013) was a look back at medical records of veterans who had x-rays taken of blockages in their coronary arteries. TRTs were not given randomly to this group, and TRT users were not compared to patients taking sugar (placebo) pills. The study suffered from blatant errors, such as including the records of 100 women in a group that should have included

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[9] Camilla M. Hoyos et al., *Body compositional and cardiometabolic effects of testosterone therapy in obese men with severe obstructive sleep apnoea: a randomised placebo-controlled trial*, 167 EURO. J. ENDOCRINOL. 531 (2012).

[10] M. Fernandez-Balsells, *Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis*, 95 J. CLIN. ENDOCRINOL. METAB. 2560, 2569, 2573 (2010).

[11] This excludes two very small studies (11 patients and 6 patients) by Charles J. Glueck in the journals *Translational Research* and *Blood Coagulation & Fibrinoloysis* about men with rare genetic defects, such as the "Factor V Leiden mutation" that no Plaintiff is alleged to have. Those studies stated they could only "speculate" that TRTs increased risk for men with those unusual defects. Charles J. Glueck et al., *Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia*, 158 TRANSLATIONAL RES. 225, 233 (2011); Charles J. Glueck et al., *Testosterone, thrombophilia, thrombosis*, BLOOD COAGULATION & FIBRINOLYSIS 4 (2014).

[12] FDA Denial at 6, 7.

only men. The senior investigator, Dr. Ho, specifically disclaimed that the study established reliable proof of causation: "it's not causal," he said. The FDA found that the *JAMA* study was set up in a way that "biased the results."[13]

The ***BMC Medicine* study** (2013) was a meta-analysis (a study of studies) purporting to find an increase in cardiovascular risk from TRTs. But the FDA rejected it, calling "into question its utility as evidence to establish a causal relationship" because of "a number of limitations," such as inappropriately excluding huge numbers of potentially relevant studies and its inclusion of a wide variety of biologically unrelated cardiovascular events. The FDA concluded that the *BMC Medicine* study "does not provide convincing evidence of a causal association."[14]

The ***PLoS One* study** (2014) was only of heart attacks, not of strokes or venous blood clots. It was a look back at health care claims data of men who used TRTs; it lacked a control group of non-users who took placebos. Instead, it compared men using TRTs to men using erectile dysfunction drugs, which the FDA found to be inappropriate. The study found *no* increased risk of heart attacks for men under 65. The FDA also criticized the study for failing to confirm that any of the men had ever actually used a TRT.

## ARGUMENT

### I. The parties should focus on general causation first.

With the FDA's consistent conclusions and the one-sided science in mind, Defendants propose a schedule that allows the Court to address general causation at the earliest practicable time. That proposal allows ample time for general causation documents to be produced, general causation depositions to be completed, and the work of general causation experts to be finished, before *Daubert* motions present the issue to the Court for a decision.

[13] FDA Denial at 12.

[14] Briefing Book, DEPI-II Qualitative Rev. at 21.

**A. This Court has the authority to prioritize general causation.**

Rule 16(c)(2)(L) authorizes this Court to enter orders "adopting special procedures for managing … protracted actions that may involve complex issues." In its discussion of Rule 16, the Manual for Complex Litigation § 11.422 advises that "initial discovery should focus on matters—witnesses, documents, information—that appear pivotal." General causation is pivotal here. "Initial discovery may also be targeted at information that might … provide the foundation for a dispositive motion…" *Id*. General causation will provide the basis for *Daubert* and/or summary judgment motions. For complex tort litigation in particular, the Manual advises judges to use Rule 16 to "take[] up early in the litigation" the issue of "whether the facts and expert evidence support a finding that the product or acts in question have the capacity to cause the type of injuries alleged…" *Id.* § 22.634; *see also Crawford-El v. Britton*, 523 U.S. 574, 598 (1998) (the court may "dictate the sequence of discovery"). That is what Defendants are proposing.

This is not the first MDL presenting threshold issues of general causation. These are examples of orders (attached for the Court's reference) entered in similar cases:

- *Incretin* (MDL 2542) (Ex. 2): as in the present case, "Defendants proposed a scheduling order that addressed *Daubert* and dispositive motions relating to general causation first, whereas Plaintiffs proposed a more standard scheduling order that addressed *Daubert* and dispositive motions after all discovery had been completed." The court ordered that general causation would go first: "initial discovery and document production will be limited to whether the requested information has some tendency in logic to prove or disprove whether Defendants' … drugs cause" the claimed injury.

- *Viagra* (MDL 1724) (Ex. 3): the court ordered that the "first phase of discovery for all cases shall be focused on the sole issue of general causation—whether Viagra is capable of causing" the claimed injury. The court cited Manual § 11.422 in support of an early resolution of this "threshold" issue. All fact and expert discovery on issues other than general causation was stayed. The court set deadlines for completing fact discovery on general causation and for expert reports and depositions on that subject.

- *Accutane* (MDL 1626) (Ex. 4): on the ground that "the admissibility of expert testimony on general causation" could be "case dispositive," the court entered a scheduling order that provided for expert reports and "initial fact discovery," followed by *Daubert* and dispositive motions. The court deferred for later setting a schedule for discovery that would take place if "the cases survive[d] the legal challenges."

- *Bextra and Celebrex* (MDL 1699) (Ex. 5): Judge Breyer (a Panel member) ordered, for cases in which the plaintiff alleged a "serious cardiovascular event" such as heart attack or stroke, an immediate schedule for "general causation experts." The schedule called for early *Daubert* motions. Expert discovery on other issues was put off.

- *Vioxx* (MDL 1657) (Ex. 6): for cases alleging heart attacks and strokes, Judge Fallon set deadlines for "generic expert report(s) on general causation" that were well before the completion of fact discovery. Expert reports were followed directly by *Daubert* and dispositive motions.

- *Vaccine Injuries* (Ex. 7): in these hundreds of cases in the National Vaccine Injury Compensation Program, alleging that vaccines caused autism, the Office of Special Masters adopted a schedule in which the Office would "[f]irst … inquire into the general causation issues involved in these cases—i.e. whether the vaccinations in question can cause autism…" That inquiry was to involve "court-approved discovery concerning the general causation issues, followed by a designation of experts for each side, an evidentiary hearing, and finally a special master's ruling on the general causation issues."

- *Chantix* (MDL 2092) (Ex. 8): defendant's document production was ordered to begin with documents relevant to general causation, followed by fact depositions of defendant's employees and then the reports of general causation and liability experts, who were subject to *Daubert* motions before the court would allow case-specific experts.

- *Zoloft* (MDL 2342) (Exs. 9 & 10): for cases alleging Zoloft caused birth defects, the court set deadlines for "Zoloft general causation and *Daubert* motions directed at Zoloft general causation experts." The court later entered an order calling for "Plaintiffs' additional generic *non-causation* expert reports and all case specific expert reports" to not be served until months after the general causation *Daubert* hearings.

In short, where general causation is a serious threshold issue, courts customize the case schedule in order to address general causation earlier in the case.

**B. General causation is a key threshold issue for these cases.**

All of Plaintiffs' claims require proof of general causation—proof the drug is capable of causing the injury. That makes general causation a key threshold issue for every Plaintiff, as their JPML brief admitted. Plaintiffs must also show that the Defendants knew or reasonably should have known the drug could cause the injury. A seller of a drug cannot warn about a risk unless "he has knowledge, or by the application of reasonable developed human skill and foresight should have knowledge," of the risk. Restatement (Second) Torts § 402A, cmt. J.[15]

There is good reason to believe that Plaintiffs can carry neither burden. Both require expert testimony, and science today does not support a reliable, admissible expert opinion that TRTs cause cardiovascular problems.

[15] *See, e.g., Moss v. Wyeth*, 872 F. Supp. 2d 162, 173 (D. Conn. 2012) (no liability for risks unless the defendant knew or should have known); *Mathews v. Novartis Pharm.*, 2013 WL 5780415, at *8 (S.D. Ohio 2013) (no liability for "a risk that is unknown and unknowable"); *Sita v. Danek Med.*, 43 F. Supp. 2d 245, 249 (E.D.N.Y. 1999) (no liability for a risk unless the defendant "knew, or, in the exercise of reasonable care, should have known to exist").

The Supreme Court has addressed this situation. In *GE v. Joiner*, 522 U.S. 136, 145 (1997), the Court excluded an expert's opinion that a chemical caused an injury, in part because the opinion was based on a study that did not reach that conclusion. "Given that [the study's authors] were unwilling to say that PCB exposure had caused cancer among the workers they examined," *id.*, the study could not support's the expert's causation opinion. "It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven." *Happel v. Walmart*, 602 F.3d 820, 826 (7th Cir. 2010) (quoting *Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009)); *see also McClain v. Metabolife Int'l*, 401 F.3d 1233, 1240 (11th Cir. 2005) (an expert may not "infer[] conclusions from studies and reports that the papers do not authorize").

That is a real problem here. In two of Plaintiffs' studies, the authors admitted they found no causation. And in all four of Plaintiffs' studies, the FDA found a lack of proof of causation. No expert can give an admissible causation opinion based on studies that do not provide it.

General causation experts must also take into account the background risk—"the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug or chemical in question." *McClain*, 401 F.3d at 1243. The background risk for heart attack and stroke are "very high," and a proper expert methodology must prove that the drug makes them even higher. *Id*. Plaintiffs' experts in the TRT cases will face that difficult challenge.

### C. Prioritizing general causation offers important advantages and no meaningful disadvantages.

The advantages to prioritizing general causation and obtaining an earlier ruling on it are obvious: if Plaintiffs fail to offer reliable expert testimony regarding general causation, the cases are over, and no additional time, money, or judicial effort need be spent on them. The second phase of discovery on defendants, about topics other than general causation, would be avoided completely, as would the need to pick bellwether plaintiffs, conduct discovery about them, prepare expert reports that are specific to their cases, and so on. General causation is a threshold

issue that deserves to be determined at the threshold of these cases, when it can still "save thousands of person-hours and millions of dollars [for] unnecessary efforts." *In re Agent Orange*, 506 F. Supp. 762, 796 (E.D.N.Y. 1980). But if *Daubert* motions are delayed to the end of the case, as Plaintiffs propose, all of this time, money, and judicial effort would likely be wasted.

Expediting a *Daubert* ruling on general causation would yield important benefits even if (against Defendants' expectation) only *some* injuries are found to lack general causation. If that were the case, the parties could then pick and take discovery on bellwether plaintiffs selected from the pool of only those with relevant injuries—rather than wasting time and money picking and taking discovery of plaintiffs who have injuries that TRTs are not even capable of causing. By contrast, Plaintiffs' proposed schedule would have all of the bellwether plaintiffs picked, all of the discovery about them done, and all of the expert reports specific to their cases done—before the Court is even asked to address whether TRTs could have caused their injuries at all.

There should be no mistake: the cost of picking bellwether plaintiffs, taking discovery about them, and expert reports about them will be very large. Under Plaintiffs' own proposal, there would be 32 bellwether plaintiffs with up to 8 depositions per plaintiff. (That number of depositions may be too low, because each plaintiff TRT user and his spouse (who is often also a plaintiff), prescriber(s), other doctor(s), and other witnesses will need to be deposed, but it is used here as an example.) That means the bellwether part of the case alone would involve up to ***256*** depositions, plus more time and money spent analyzing medical records to pick the bellwethers in the first place, plus a lot of added time and money for expert witnesses. All of that expense will prove wasteful if, as the science shows, Plaintiffs are not able to offer reliable expert testimony regarding general causation.

Joining all these important advantages are no meaningful disadvantages to Plaintiffs. The general causation fact discovery and expert work must be done in any event, so pushing it to the fore hurts no one. And the savings in time and money described above will equally benefit both parties. Plaintiffs and their counsel too will benefit by knowing sooner rather than later whether to continue spending money on cases that lack the necessary merit to proceed.

When the parties conferred about the schedule, Plaintiffs argued that sequencing discovery of defendants into general causation first, with other discovery to follow, will result in witnesses being deposed twice because they have knowledge in both areas. Defendants think that witnesses with deposition-worthy knowledge in both areas will be rare or (more likely) nonexistent. Most employees' job responsibilities do not span drug safety and entirely unrelated issues. In any event, if such a witness were to appear, the parties could confer over the best way to handle it. The possible existence of this unlikely, small-scale scenario is not a good reason to avoid the substantial advantages that a schedule prioritizing general causation will bring. The same is true of another argument Plaintiffs made, that there could be disputes about whether a particular item in discovery relates to general causation or not. Defendants believe the parties will be able to confer and resolve any such issues without the Court's assistance.

## II. Even aside from its untimely treatment of general causation, Plaintiffs' proposed schedule is seriously flawed.

Plaintiffs' overall schedule is simply unrealistic. It proposes that the first trial will begin less than 18 months from today, even though this MDL was only recently formed and the foundational case management orders are still being negotiated. The *median* case in this District takes almost *36 months* to get to trial.[16] And of course this MDL is not an average case. There are six main Defendants and several smaller ones, with over 300 separate lawsuits and more being filed every day. Millions of pages of documents will be produced. Many witnesses will be deposed. The volume of activity will vastly exceed an ordinary case. Yet Plaintiffs' proposal gives the parties *less than half* of the time that an average case takes to get to trial.

Defendants' proposed schedule, while aggressive, attempts to be realistic. It calls for the first trial to begin around 36 months from now. It will take a herculean effort to make that happen, but it is at least within the realm of possibility. Squeezing huge document productions,

[16] U.S. Courts, *United States District Courts—National Judicial Caseload Profile*, at 47 of 95 (12 months ending June 30, 2014), *available at* http://www.uscourts.gov/viewer.aspx?doc=/uscourts/Statistics/FederalCourtManagementStatistics/2014/district-fcms-profiles-june2014.pdf&page=47 (35.4 months).

depositions of numerous witnesses from each Defendant, the hundreds of bellwether-related depositions that Plaintiffs believe will be taken, the work of many experts, and all of the rest into the tiny schedule Plaintiffs propose is not possible. It guarantees that the parties will soon start calling on the Court for extension after extension.

A second central defect in Plaintiffs' proposal is that it calls for bellwether plaintiffs to be picked far too early, in April 2015. At that time, relatively few of the cases will be on file—there are around 300 on file today, and Plaintiffs' counsel leadership represented to the court that they have roughly 6,000 clients under contract. In addition, the process of collecting the Plaintiffs' medical records takes months, so by April Defendants will not even have the complete medical files for the 300 cases already on file, much less for cases that are filed later. And of course the often voluminous records take a lot of time to analyze before bellwether selections are made. If bellwethers are picked in April, Defendants will be in the dark and the deck will be even more stacked. That would deprive the bellwethers of their essential value, because they are useful as test cases only if both sides actually believe they are representative and therefore informative.

To avoid these problems, Defendants' proposal calls for bellwethers to be picked later in the case (or perhaps not at all, depending on how general causation is resolved). At that point, a greater number of cases will be on file and far more medical records will have been collected. Both sides will be better informed about which bellwethers may be representative, and the bellwether process will have its intended value.

On a similar note, Plaintiffs' proposed schedule also makes the mistake of trying to set the parameters of bellwether selection now, long before enough information is known. Plaintiffs' proposal divides bellwethers into "two tiers of cases: (1) Venous Thromboembolism ('VTE') clotting injury cases (*e.g.*, deep vein thrombosis ('DVT'), Pulmonary Embolism ('PE'), or other clotting cases); and (2) cardiovascular cases (*e.g.*, heart attack or ischemic stroke cases)," specifying how many of each type of bellwether there will be for discovery, how many of each type there will be for trial, the order in which they will be tried, and so on. It is far too early to know any of this information (but the fact that Plaintiffs' proposal separates venous blood clots

from other injuries indicates that Plaintiffs believe there may be notable differences between those injuries, which again shows that the Court should address general causation before bellwether Plaintiffs are picked). Again, only a small fraction of the expected number of cases is even on file, and medical record collection will not begin until 2015. Defendants' proposal avoids these problems by establishing a date, sufficiently far into the case, on which the parties can come to an agreement on bellwether selection processes and parameters.

## CONCLUSION

For the foregoing reasons, Defendants respectfully urge the Court to enter the case management order attached hereto as Ex. 1.

Dated: October 20, 2014

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Scott Ahmad, hereby certify that on October 20, 2014, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

*/s/ Shawn J. Gebhardt*